

### REMARKS

This preliminary amendment accompanies a Request for Continued Examination (RCE).

Claims 1-11 and 19-43 are pending. Of those, claims 19-29 were previously withdrawn from consideration. Claims 41-43 are new. Support for new claims 41-43 can be found, for example, in the figures. No new matter has been added.

Applicant asks that all claims be examined in view of the amendment to the claims.

#### Rejections based on U.S. Patent Application Publication No. 2003/0100830 (Zhong)

Claims 1-3, 5, 6, 10, 11, 34, 36 and 38-40 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent Application Publication No. 2003/0100830 (Zhong). Applicants disagree with these rejections.

Claim 1 recites a support structure formed such that magnetic field changes in a region immediately proximate the support structure, induced by a magnetic resonance imaging process, are substantially unobstructed and a magnetic material at least embedded into at least part of the support structure. The Zhong et al. publication neither discloses nor renders obvious the claimed subject matter.

The Zhong publication discloses providing a hydrogel polymer as a coating for an insertable or implantable medical device. *See* Zhong, ¶¶ 26, 29, 46 and 52. In some embodiments, the hydrogel polymer incorporates paramagnetic material therein. *See* Zhong, ¶¶ 53. Applicants previously established that the Zhong coating is not “embedded” into the implantable medical device. Under this rejection, the Examiner incorrectly alleges that the Zhong coating corresponds to the “support structure” recited in claim 1.

The Zhong coating is not formed such that magnetic field changes in a region immediately proximate the Zhong coating, induced by a magnetic resonance imaging process, are substantially unobstructed, as recited in claim 1. Instead, the Zhong publication makes clear that the Zhong coating, regardless of whether it includes paramagnetic material, renders the insertable or implantable medical device visible under magnetic resonance imaging. *See, e.g.*, ¶

26. Since the Zhong coating renders the insertable or implantable medical device visible under magnetic resonance imaging, it follows that magnetic field changes in a region immediately proximate the Zhong coating are at least somewhat obstructed. Certainly the magnetic field changes are not “substantially unobstructed,” as recited in claim 1.

For at least the foregoing reasons, the Zhong coating does not correspond to the “support structure” recited in claim 1.

Claim 1 is not anticipated by the Zhong publication for at least the foregoing reasons.

Claim 1 also is not obvious over the Zhong publication.

Zong may not preclude patentability of the claimed subject matter because the present application was subject to an obligation of assignment to the common assignee of the Zong publication at the time the claimed invention was made. Indeed, 35 U.S.C. § 103(c)(1) states:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The present application was subject to an obligation of assignment from the inventors to Scimed Life Systems, Inc., as of the filing date of September 24, 2003. The assignment was recorded in the USPTO on September 24, 2003 at Reel No. 04573, Frame No. 0282. At the time the claimed invention was made, the Zong publication was also assigned to Scimed Life Systems, Inc., by assignment from the inventors and recorded in the USPTO on February 12, 2002 at Reel No. 012664, Frame No. 0515. As such, the Examiner's rejection under 35 U.S.C. §103(a) is improper and should be withdrawn.

Additionally, under the obviousness-type rejection of claim 1, the Examiner alleges that “it would have been an obvious matter of design choice . . . to embed the magnetic material into at least part of the support structure since the applicant discloses the magnetic material may be

coated on the support structure and has not disclosed that embedding the magnetic material into at least part of the support structure solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with a magnetic coating.” Applicants disagree.

First, as Applicants previously pointed out in the *Pre-Appeal Brief Request for Review*, which was filed on December 10, 2007, the Background section of the Zhong publication identifies several reasons why magnetic material should not be embedded into implantable medical devices. The Background section identifies numerous drawbacks associated with the embedded ferromagnetic particles, stating that:

“[t]he direct incorporation of ferromagnetic or paramagnetic materials into the polymeric material of ... implantable or insertable medical devices, however, suffers from numerous drawbacks. For example, in order to provide enhanced contrast under MRI, paramagnetic materials, such as paramagnetic ions, require the proximity of water or another proton-bearing substance.... Moreover, the incorporation of such ferromagnetic or paramagnetic materials can detrimentally affect the requisite mechanical properties, such as strength and flexibility, of the polymeric materials used to construct the implantable or insertable medical device.”

(Zhong, ¶ 0009).

The Background section of Zhong et al. concludes that “there remains a need for [an] approach that avoids the disadvantages of the methods discussed above.” Then, the Zhong et al publication discloses, presumably in an attempt to overcome the drawbacks identified in the excerpted passage above, coating an implantable medical device with a hydrogel polymer that is adapted to incorporate a paramagnetic material. (Zhong, ¶53; see also Zhong, ¶¶ 26, 29, and 46).

In view of the foregoing, a person of ordinary skill would have understood not to modify the Zhong approach to include embedding. And that person would not have considered such modification to be an obvious matter of design choice, as suggested by the Examiner.

Moreover, “[t]o reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” MPEP 2142. Indeed, “[k]nowledge of applicant’s disclosure must be put aside in reaching this determination.” *Id.*

The rejection of claim 1 is improper, because the Examiner did not put aside the Applicant's disclosure to reach the obviousness determination. Instead, as evidenced by the statement that "it would have been an obvious matter of design choice . . . *since the applicant discloses . . .*" (*emphasis added*), the Examiner clearly did not put aside the Applicant's disclosure to reach the obviousness determination. Instead, the Examiner relied on the applicant's disclosure ("since the applicant discloses") to reach the obviousness determination. Applicants respectfully submit that such reliance was improper.

Claim 1 should be allowable over the Zhong publication for at least the foregoing reasons.

Claims 2, 3, 5, 6, 8, 10 and 11 depend from claim 1 and, therefore, should be allowable over the Zhong publication for at least the same reasons as claim 1.

Claim 34 recites subject matter similar to claim 1. More particularly, claim 34 recites a structure made of a metallic material that is substantially non-magnetic and a magnetic material at least embedded into the metallic material for rendering the structure visible during a magnetic resonance imaging procedure. For at least the reasons discussed above with reference to claim 1, the Zhong publication does not disclose or render obvious the claimed subject matter.

Claim 34 is allowable over the Zhong publication for at least the foregoing reasons.

Claims 36 and 38-40 depend from claim 34 and, therefore, should be allowable over the Zhong publication for at least the same reasons as claim 34.

#### Rejections based on U.S. Patent No. 6,361,759 (Frayne)

Claims 1, 7 and 9 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,361,759 (Frayne). Applicants disagree with these rejections.

As indicated above, claim 1 recites a support structure formed such that magnetic field changes in a region immediately proximate the support structure, induced by a magnetic resonance imaging process, are substantially unobstructed and a magnetic material at least embedded into at least part of the support structure. The Frayne patent does not disclose or render obvious the claimed subject matter.

The Frayne patent discloses an MRI signal-emitting coating. *See, e.g.*, Frayne's title. More particularly, Frayne discloses applying a coating that emits a magnetic resonance signal onto a medical device so that the medical device will be visible during magnetic resonance imaging. *See* col. 1, lines 20-27; col. 8, lines 4-14 and 48-55. Under this rejection the Examiner alleges that the Frayne coating corresponds to the "support structure" recited in claim 1. That is incorrect.

The Frayne coating is not formed such that magnetic field changes in a region immediately proximate the Frayne coating, induced by a magnetic resonance imaging process, are substantially unobstructed, as recited in claim 1. Instead, as pointed out above, the Frayne coating emits a magnetic resonance signal to a medical device so that the medical device will be visible during magnetic resonance imaging. *See* col. 1, lines 20-27. Since the Frayne coating renders the medical device visible under magnetic resonance imaging, it is not formed such that magnetic field changes in a region immediately proximate the Frayne coating are substantially unobstructed, as recited in claim 1.

For at least the foregoing reasons, the Frayne coating does not correspond to the "support structure" recited in claim 1.

Claim 1 is not anticipated by the Frayne patent for at least the foregoing reasons.

Claims 1 also is not obvious over the Frayne patent.

Under the obviousness-type rejection of claim 1, the Examiner alleges that "it would have been an obvious matter of design choice . . . to embed the magnetic material into at least part of the support structure *since the applicant discloses* the magnetic material may be coated on the support structure and has not disclosed that embedding the magnetic material into at least part of

the support structure solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with a magnetic coating.” *Emphasis added*. Applicants disagree.

As discussed above, “[t]o reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” MPEP 2142. Indeed, “[k]nowledge of applicant’s disclosure must be put aside in reaching this determination.” *Id.* The rejection of claim 1 is improper, because the Examiner did not put aside the Applicant’s disclosure to reach the obviousness determination. Instead, as evidenced by the statement that “it would have been an obvious matter of design choice . . . *since the applicant discloses . . .*” (*emphasis added*), the Examiner clearly did not put aside the Applicant’s disclosure to reach the obviousness determination. Instead, the Examiner relied on the applicant’s disclosure (“since the applicant discloses”) to reach the obviousness determination. Applicants respectfully submit that such reliance was improper.

Moreover, Applicants do not concede that a coating of magnetic material would perform equally well as “a magnetic material embedded into at least part of the support structure,” as the Office action suggests. Indeed, in some implementations, embedding magnetic material in the support structure provides a degree of durability that might be absent in a mere coating.

Claim 1 should be allowable over the Frayne patent for at least the foregoing reasons.

Claims 7 and 9 depend from claim 1 and, therefore, should be allowable over the Frayne patent for at least the same reasons as claim 1.

Rejections based on the Zhong publication and U.S. Patent No. 6,921,414 (Klumb)

Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over the Zhong publication in view of U.S. Patent No. 6,921,414 (Klumb).

Claim 4 depends from claim 1, which recites a support structure formed such that magnetic field changes in a region immediately proximate the support structure, induced by a

magnetic resonance imaging process, are substantially unobstructed and a magnetic material at least embedded into at least part of the support structure. As discussed above, the Zhong publication does not disclose or render obvious the claimed subject matter. Nor does the Klumb patent disclose or suggest the claimed subject matter.

The Klumb patent discloses a prosthesis with a coiled body and a graft material covering at least part of the coiled body. *See* Abstract. The graft material is not a magnetic material at least embedded into at least part of a support structure, as recited in claim 1. The Office action itself concedes this point. (Office action, top of p. 7 “Klumb et al. do not disclose . . . that magnetic material is at least embedded into the segment.”). Nor would any reasonable combination of Zhong and Klumb result in the claimed subject matter.

Claim 4 should be allowable over the Zhong publication in view of the Klumb patent for at least the foregoing reasons.

Claim 35 also was rejected under 35 U.S.C. §103(a) as being unpatentable over the Zhong publication in view of the Klumb patent.

Claim 35 depends from claim 34, which recites subject matter similar to claim 1, discussed above. More particularly, claim 34 recites a structure made of a metallic material that is substantially non-magnetic and a magnetic material at least embedded into the metallic material for rendering the structure visible during a magnetic resonance imaging procedure. For reasons similar to those discussed above with reference to claims 4 and 1, neither the Zhong publication, nor the Klumb patent, nor any combination thereof, discloses or renders obvious the claimed subject matter.

Claim 35 should be allowable for at least the foregoing reasons.

Claims 30-33 also were rejected under 35 U.S.C. §103(a) as being unpatentable over the Zhong publication in view of the Klumb patent.

Claim 30 recites a support structure including a segment of material and a magnetic material at least embedded into the segment. For at least the reasons discussed above, neither the

Zhong publication, nor the Klumb patent, nor any combination thereof, discloses or renders obvious the claimed subject matter.

Claim 30 should be allowable for at least the foregoing reasons.

Claims 31-33 depend from claim 30 and, therefore, should be allowable for at least the same reasons as claim 30.

### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The excess claims fee in the amount of \$570.00 and the Request for Continued Examination (RCE) fee in the amount of \$810.00 are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account Authorization. Please apply any other charges or credits to deposit account 06-1050.



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